

AMENDED IN ASSEMBLY AUGUST 25, 2005

AMENDED IN ASSEMBLY AUGUST 15, 2005

AMENDED IN SENATE APRIL 18, 2005

SENATE BILL

No. 734

Introduced by Senator Torlakson

February 22, 2005

An act to amend Sections 11159.2, 11161, 11161.5, 11162.1, 11164, and 11190 of, and to add and repeal Section 11165.5 of, the Health and Safety Code, relating to controlled substances, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 734, as amended, Torlakson. Controlled substances.

(1) Existing law provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements.

This bill would provide that a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a form that does not contain certain other features, as specified.

(2) Existing law provides that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court, upon the motion of a law enforcement agency, shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order.

This bill would require the court, in its order, to also prohibit the practitioner from obtaining, ordering, or using any additional prescription forms. The bill would impose a state-mandated local program by requiring the law enforcement agency obtaining the order

to notify the Department of Justice of the order. The bill would make clarifying and conforming changes to this and related provisions.

(3) Existing law provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy; the board may approve security printer applications after the applicant has provided specified information and the applicant's fingerprints, in a manner specified by the board, for the purpose of completing state and federal criminal background checks.

This bill would revise the latter provision to provide instead that the prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice and that the department shall provide the applicant with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks. The bill would provide that the applicant shall submit his or her fingerprint images and related information to the department for the purpose of the department obtaining information as to the existence and nature of a record of specified state, federal, or foreign level convictions and arrests. Requests for federal level criminal offender record information received by the department shall be forwarded to the Federal Bureau of Investigation by the department. The bill would provide that the department shall assess the applicant a fee sufficient to cover all processing or maintenance costs of the department associated with providing the background checks, as specified.

(4) Existing law provides that the Board of Pharmacy or the Department of Justice may deny a security printer application for specified reasons, including that the applicant has been convicted of a crime.

This bill would provide that the Department of Justice, but not the Board of Pharmacy, may deny the security printer application for the specified reasons, including if any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant who has direct access, management, or control of controlled substance prescription forms has been convicted of a crime. The bill would also add as a condition for approval as a security printer that the applicant authorize the department to make any examination of books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed

necessary by the board or department to properly enforce the provisions relating to security printers. An approved applicant would be required to submit an exemplar of a controlled substance prescription form, with all security features, to the department within 30 days of initial production.

(5) Existing law provides that prescription forms shall be printed with specified features.

This bill would provide that prescription forms shall also include the feature of an identifying number assigned to the approved security printer by the Department of Justice. The bill would also require the forms to set forth specified information, as appropriate, with respect to multiple prescribers.

(6) Existing law provides that controlled substances in Schedule III, IV, or V may be dispensed upon an oral electronically transmitted prescription.

This bill would require persons who transmit or receive any oral or electronically transmitted prescription to ensure its integrity and confidentiality.

(7) Existing law provides for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program.

This bill would provide that the Board of Pharmacy shall, contingent upon the availability of adequate funds, evaluate the viability of implementing real time reporting, as defined, and access to data on controlled substances in the operation of CURES. This bill would provide that *these provisions shall be implemented to the extent that sufficient nonstate funds are received to cover the costs to the Board of Pharmacy of providing staff and for the preparation of the report; and that any nonstate funds donated funds for that purpose* are appropriated to the board for that purpose.

(8) Existing law generally provides that a violation of the provisions relating to the prescription of controlled substances is a misdemeanor, punishable as specified. This bill, to the extent it revises existing crimes, would impose a state-mandated local program upon local governments.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority. Appropriation: yes. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 11159.2 of the Health and Safety Code
2 is amended to read:

3 11159.2. (a) Notwithstanding any other provision of law, a
4 prescription for a controlled substance for use by a patient who
5 has a terminal illness may be written on a prescription form that
6 does not meet the requirements of Section 11162.1 if the
7 prescription meets the following requirements:

8 (1) Contain the information specified in subdivision (a) of
9 Section 11164.

10 (2) Indicate that the prescriber has certified that the patient is
11 terminally ill by the words "11159.2 exemption."

12 (b) A pharmacist may fill a prescription pursuant to this
13 section when there is a technical error in the certification
14 required by paragraph (2) of subdivision (a), provided that he or
15 she has personal knowledge of the patient's terminal illness, and
16 subsequently returns the prescription to the prescriber for
17 correction within 72 hours.

18 (c) For purposes of this section, "terminally ill" means a
19 patient who meets all of the following conditions:

20 (1) In the reasonable medical judgment of the prescribing
21 physician, the patient has been determined to be suffering from
22 an illness that is incurable and irreversible.

23 (2) In the reasonable medical judgment of the prescribing
24 physician, the patient's illness will, if the illness takes its normal
25 course, bring about the death of the patient within a period of one
26 year.

27 (3) The patient's treatment by the physician prescribing a
28 ~~Schedule H~~ controlled substance pursuant to this section

1 primarily is for the control of pain, symptom management, or
2 both, rather than for cure of the illness.

3 (d) This section shall become operative on July 1, 2004.

4 SEC. 2. Section 11161 of the Health and Safety Code is
5 amended to read:

6 11161. (a) When a practitioner is named in a warrant of
7 arrest or is charged in an accusatory pleading with a felony
8 violation of Section 11153, 11154, 11156, 11157, 11170, 11173,
9 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5,
10 11379, 11379.5, or 11379.6, the court in which the accusatory
11 pleading is filed or the magistrate who issued the warrant of
12 arrest shall, upon the motion of a law enforcement agency which
13 is supported by reasonable cause, issue an order which requires
14 the practitioner to surrender to the clerk of the court all controlled
15 substance prescription forms in the practitioner's possession at a
16 time set in the order and which prohibits the practitioner from
17 obtaining, ordering, or using any additional prescription forms.
18 The law enforcement agency obtaining the order shall notify the
19 Department of Justice of this order. Except as provided in
20 subdivisions (b) and (e) of this section, the order shall remain in
21 effect until further order of the court. Any practitioner possessing
22 prescription forms in violation of the order is guilty of a
23 misdemeanor.

24 (b) The order provided by subdivision (a) shall be vacated if
25 the court or magistrate finds that the underlying violation or
26 violations are not supported by reasonable cause at a hearing held
27 within two court days after the practitioner files and personally
28 serves upon the prosecuting attorney and the law enforcement
29 agency that obtained the order, a notice of motion to vacate the
30 order with any affidavits on which the practitioner relies. At the
31 hearing, the burden of proof, by a preponderance of the evidence,
32 is on the prosecution. Evidence presented at the hearing shall be
33 limited to the warrant of arrest with supporting affidavits, the
34 motion to require the defendant to surrender controlled substance
35 prescription forms and to prohibit the defendant from obtaining,
36 ordering, or using controlled substance prescription forms, with
37 supporting affidavits, the sworn complaint together with any
38 documents or reports incorporated by reference thereto which, if
39 based on information and belief, state the basis for the
40 information, or any other documents of similar reliability as well

1 as affidavits and counter affidavits submitted by the prosecution
2 and defense. Granting of the motion to vacate the order is no bar
3 to prosecution of the alleged violation or violations.

4 (c) The defendant may elect to challenge the order issued
5 under subdivision (a) at the preliminary examination. At that
6 hearing, the evidence shall be limited to that set forth in
7 subdivision (b) and any other evidence otherwise admissible at
8 the preliminary examination.

9 (d) If the practitioner has not moved to vacate the order issued
10 under subdivision (a) by the time of the preliminary examination
11 and he or she is held to answer on the underlying violation or
12 violations, the practitioner shall be precluded from afterwards
13 moving to vacate the order. If the defendant is not held to answer
14 on the underlying charge or charges at the conclusion of the
15 preliminary examination, the order issued under subdivision (a)
16 shall be vacated.

17 (e) Notwithstanding subdivision (d), any practitioner who is
18 diverted pursuant to Chapter 2.5 (commencing with Section
19 1000) of Title 7 of Part 2 of the Penal Code may file a motion to
20 vacate the order issued under subdivision (a).

21 (f) This section shall become operative on November 1, 2004.

22 SEC. 3. Section 11161.5 of the Health and Safety Code is
23 amended to read:

24 11161.5. (a) Prescription forms for controlled substance
25 prescriptions shall be obtained from security printers approved
26 by the Department of Justice.

27 (b) The department may approve security printer applications
28 after the applicant has provided the following information:

29 (1) Name, address, and telephone number of the applicant.

30 (2) Policies and procedures of the applicant for verifying the
31 identity of the prescriber ordering controlled substance
32 prescription forms.

33 (3) Policies and procedures of the applicant for verifying
34 delivery of controlled substance prescription forms to
35 prescribers.

36 (4) (A) The location, names, and titles of the applicant's agent
37 for service of process in this state; all principal corporate officers,
38 if any; and all managing general partners, if any.

1 (B) A report containing this information shall be made on an
2 annual basis and within 30 days after any change of office,
3 principal corporate officers, or managing general partner.

4 (5) (A) A signed statement indicating whether the applicant,
5 principal corporate officers, or managing general partners have
6 ever been convicted of, or pled no contest to, a violation of any
7 law of a foreign country, the United States, or any state, or of any
8 local ordinance.

9 (B) The department shall provide the applicant with the means
10 and direction to provide fingerprints and related information, in a
11 manner specified by the department, for the purpose of
12 completing state, federal, or foreign criminal background checks.

13 (C) Any applicant described in subdivision (b) shall submit his
14 or her fingerprint images and related information to the
15 department, for the purpose of the department obtaining
16 information as to the existence and nature of a record of state,
17 federal, or foreign level convictions and state, federal, or foreign
18 level arrests for which the department establishes that the
19 applicant was released on bail or on his or her own recognizance
20 pending trial, as described in subdivision (l) of Section 11105 of
21 the Penal Code. Requests for federal level criminal offender
22 record information received by the department pursuant to this
23 section shall be forwarded to the Federal Bureau of Investigation
24 by the department.

25 (D) The department shall assess against each applicant a fee
26 determined by the department to be sufficient to cover all
27 processing, maintenance, and investigative costs generated from
28 or associated with completing state, federal, or foreign
29 background checks pursuant to this section with respect to that
30 applicant; the fee shall be paid by the applicant at the time he or
31 she submits fingerprints and related information to the
32 department.

33 (E) The department shall retain fingerprint impressions and
34 related information for subsequent arrest notification pursuant to
35 Section 11105.2 of the Penal Code for all applicants.

36 (c) The department may, within 60 calendar days of receipt of
37 the application from the applicant, deny the security printer
38 application.

39 (d) The department may deny a security printer application on
40 any of the following grounds:

(1) The applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.

(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.

(3) The applicant committed any act that would constitute a violation of this division.

(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.

(5) The department determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.

(6) The department determines that the applicant has submitted an incomplete application.

(7) As a condition for its approval as a security printer, an applicant shall authorize the Department of Justice to make any examination of the books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.

(e) An approved applicant shall submit an exemplar of a controlled substance prescription form, with all security features, to the Department of Justice within 30 days of initial production.

(f) The department shall maintain a list of approved security printers and the department shall make this information available to prescribers and other appropriate government agencies, including the Board of Pharmacy.

1 (g) Before printing any controlled substance prescription
2 forms, a security printer shall verify with the appropriate
3 licensing board that the prescriber possesses a license and current
4 prescribing privileges which permits the prescribing of controlled
5 substances.

6 (h) Controlled substance prescription forms shall be provided
7 directly to the prescriber either in person, by certified mail, or by
8 a means that requires a signature signifying receipt of the
9 package and provision of that signature to the security printer.

10 (i) Security printers shall retain ordering and delivery records
11 in a readily retrievable manner for individual prescribers for three
12 years.

13 (j) Security printers shall produce ordering and delivery
14 records upon request by an authorized officer of the law as
15 defined in Section 4017 of the Business and Professions Code.

16 (k) (1) The department may revoke its approval of a security
17 printer for a violation of this division or action that would permit
18 a denial pursuant to subdivision (d) of this section.

19 (2) When the department revokes its approval, it shall notify
20 the appropriate licensing boards and remove the security printer
21 from the list of approved security printers.

22 SEC. 4. Section 11162.1 of the Health and Safety Code is
23 amended to read:

24 11162.1. (a) The prescription forms for controlled substances
25 shall be printed with the following features:

26 (1) A latent, repetitive “void” pattern shall be printed across
27 the entire front of the prescription blank; if a prescription is
28 scanned or photocopied, the word “void” shall appear in a pattern
29 across the entire front of the prescription.

30 (2) A watermark shall be printed on the backside of the
31 prescription blank; the watermark shall consist of the words
32 “California Security Prescription.”

33 (3) A chemical void protection that prevents alteration by
34 chemical washing.

35 (4) A feature printed in thermo-chromic ink.

36 (5) An area of opaque writing so that the writing disappears if
37 the prescription is lightened.

38 (6) A description of the security features included on each
39 prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form and the following quantities shall appear:

1-24

25-49

50-74

75-100

101-150

151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the “Prescription is void if the number of drugs prescribed is not noted.”

(9) The preprinted name, category of licensure, license number, federal controlled substance registration number of the prescribing practitioner.

(10) A check box indicating the prescriber’s order not to substitute.

(11) An identifying number assigned to the approved security printer by the Department of Justice.

(12) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by their name.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated

1 prescriber and the name, address, category of licensure, and
2 license number of the licensed health care facility the clinic
3 specified in Section 1200, or the clinic specified in subdivision
4 (a) of Section 1206 that has 25 or more physicians or surgeons
5 preprinted on the form.

6 (3) Forms ordered pursuant to this section shall not be valid
7 prescriptions without the name, category of licensure, license
8 number, and federal controlled substance registration number of
9 the prescriber on the form.

10 (4) (A) Except as provided in subparagraph (B), the designated
11 prescriber shall maintain a record of the prescribers to whom the
12 controlled substance prescription forms are issued, that shall
13 include the name, category of licensure, license number, federal
14 controlled substance registration number, and the quantity of
15 controlled substance prescription forms issued to each prescriber
16 and be maintained in the health facility for three years.

17 (B) Forms ordered pursuant to this subdivision that are printed
18 by a computerized prescription generation system shall not be
19 subject to the requirements set forth in subparagraph (A) or
20 paragraph (7) of subdivision (a). Forms printed pursuant to this
21 subdivision that are printed by a computerized prescription
22 generation system may contain the prescriber's name, category of
23 professional licensure, license number, federal controlled
24 substance registration number, and the date of the prescription.

25 (d) This section shall become operative on July 1, 2004.

26 SEC. 5. Section 11164 of the Health and Safety Code is
27 amended to read:

28 11164. Except as provided in Section 11167, no person shall
29 prescribe a controlled substance, nor shall any person fill,
30 compound, or dispense a prescription for a controlled substance,
31 unless it complies with the requirements of this section.

32 (a) Each prescription for a controlled substance classified in
33 Schedule II, III, IV, or V, except as authorized by subdivision
34 (b), shall be made on a controlled substance prescription form as
35 specified in Section 11162.1 and shall meet the following
36 requirements:

37 (1) The prescription shall be signed and dated by the
38 prescriber in ink and shall contain the prescriber's address and
39 telephone number; the name of the person for whom the
40 controlled substance is prescribed; and the name, quantity,

1 strength, and directions for use of the controlled substance
2 prescribed.

3 (2) The prescription shall also contain the address of the
4 person for whom the controlled substance is prescribed. If the
5 prescriber does not specify this address on the prescription, the
6 pharmacist filling the prescription or an employee acting under
7 the direction of the pharmacist shall write or type the address on
8 the prescription or maintain this information in a readily
9 retrievable form in the pharmacy.

10 (b) (1) Notwithstanding paragraph (1) of subdivision (a) of
11 Section 11162.1, any controlled substance classified in Schedule
12 III, IV, or V may be dispensed upon an oral or electronically
13 transmitted prescription, which shall be produced in hard copy
14 form and signed and dated by the pharmacist filling the
15 prescription or by any other person expressly authorized by
16 provisions of the Business and Professions Code. Any person
17 who transmits, maintains, or receives any electronically
18 transmitted prescription shall ensure the security, integrity,
19 authority, and confidentiality of the prescription.

20 (2) The date of issue of the prescription and all the information
21 required for a written prescription by subdivision (a) shall be
22 included in the written record of the prescription; the pharmacist
23 need not include the address, telephone number, license
24 classification, or federal registry number of the prescriber or the
25 address of the patient on the hard copy, if that information is
26 readily retrievable in the pharmacy.

27 (3) Pursuant to an authorization of the prescriber, any agent of
28 the prescriber on behalf of the prescriber may orally or
29 electronically transmit a prescription for a controlled substance
30 classified in Schedule III, IV, or V, if in these cases the written
31 record of the prescription required by this subdivision specifies
32 the name of the agent of the prescriber transmitting the
33 prescription.

34 (c) The use of commonly used abbreviations shall not
35 invalidate an otherwise valid prescription.

36 (d) Notwithstanding any provision of subdivisions (a) and (b),
37 prescriptions for a controlled substance classified in Schedule V
38 may be for more than one person in the same family with the
39 same medical need.

40 (e) This section shall become operative on January 1, 2005.

1 SEC. 6. Section 11165.5 is added to the Health and Safety
2 Code, to read:

3 11165.5. (a) The Board of Pharmacy shall, contingent upon
4 the availability of adequate funds, evaluate the viability of the
5 implementing real time reporting and access to data on
6 prescriptions for controlled substances in the operation of the
7 Controlled Substances Utilization Review and Evaluation System
8 (CURES). For the purposes of this subdivision, “real time
9 reporting” means the ability to send and access prescription data
10 instantaneously in the operation of CURES.

11 (b) The Board of Pharmacy, in consultation with the Medical
12 Board of California and Department of Justice, shall contract
13 with a vendor to prepare a feasibility study report in accordance
14 with the State Administrative Manual (SAM) to analyze the
15 costs, benefits, and processes necessary to implement real time
16 reporting of controlled substances in the operation of CURES.

17 (c) This section shall be implemented to the extent that
18 sufficient nonstate funds are received to cover the costs to the
19 Board of Pharmacy of providing staff, ~~support for the~~
20 ~~commission~~, and for the preparation of the report. The costs
21 incurred by the Board of Pharmacy implementing this section
22 shall be solicited and funded from nongovernmental entities. It is
23 not the responsibility of the Board of Pharmacy to solicit the
24 funds for this study. The costs for the feasibility study report and
25 the staff to support the preparation of the report shall be no more
26 than two hundred fifty thousand dollars (\$250,000). Any nonstate
27 funds donated for that purpose are appropriated to the Board of
28 Pharmacy for that purpose.

29 (d) The board shall submit the feasibility study report to the
30 Legislature on or before July 1, 2007, or within 18 months of
31 receipt of sufficient funding, whichever date is later.

32 (e) This section shall remain in effect until January 1, 2008,
33 and as of that date is repealed, unless a later enacted statute, that
34 becomes operative on or before January 1, 2008, deletes or
35 extends that date.

36 SEC. 7. Section 11190 of the Health and Safety Code is
37 amended to read:

38 11190. (a) Every practitioner, other than a pharmacist, who
39 prescribes or administers a controlled substance classified in

Schedule II shall make a record that, as to the transaction, shows all of the following:

(1) The name and address of the patient.

(2) The date.

(3) The character, including the name and strength, and quantity of controlled substances involved.

(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II or Schedule III controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:

(A) Full name, address, gender, and date of birth of the patient.

(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(C) NDC (National Drug Code) number of the controlled substance dispensed.

(D) Quantity of the controlled substance dispensed.

(E) ICD-9 (diagnosis code), if available.

(F) Date of dispensing of the prescription.

(2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in a format set by the Department of Justice pursuant to regulation.

(d) This section shall become operative on January 1, 2005.

SEC. 8. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution for certain costs that may be incurred by a local agency or school district because, in that regard, this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

1 However, if the Commission on State Mandates determines
2 that this act contains other costs mandated by the state,
3 reimbursement to local agencies and school districts for those
4 costs shall be made pursuant to Part 7 (commencing with Section
5 17500) of Division 4 of Title 2 of the Government Code.

O